

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF NEW YORK

---

UNITED STATES OF AMERICA

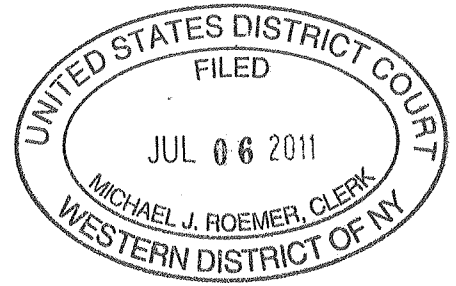
-v-

10-CR-307-A

ANTHONY GALEA,

Defendant.

---



**PLEA AGREEMENT**

The defendant, ANTHONY GALEA, and the United States Attorney for the Western District of New York (hereinafter "the government") hereby enter into a plea agreement with the terms and conditions as set out below.

**I. THE PLEA AND POSSIBLE SENTENCE**

1. The defendant agrees to plead guilty to Count III of the Indictment, charging a violation of Title 21, United States Code, Sections 331(a) and 333(a)(2) (introducing misbranded drugs into interstate commerce with intent to mislead an agency of the United States), for which the maximum sentence is a term of imprisonment of three years, a fine of \$250,000, a mandatory \$100 special assessment and a term of supervised release of one year. The defendant understands that the penalties set forth in this paragraph are the maximum penalties that can be imposed by the Court at sentencing.

2. The defendant understands that, if it is determined that he has violated any of the terms or conditions of supervised release, he may be required to serve in prison all or part of the term of supervised release, up to one year, without credit for time previously served on supervised release. As a consequence, in the event the defendant is sentenced to the maximum term of incarceration, a prison term imposed for a violation of supervised release may result in the defendant serving a sentence of imprisonment longer than the statutory maximum set forth in paragraph 1 of this agreement.

## **II. ELEMENTS OF THE CRIME AND FACTUAL BASIS**

3. The defendant understands the nature of the offense set forth in paragraph 1 of this agreement and understands that if the case proceeded to trial, the government would be required to prove beyond a reasonable doubt each of the following elements of the crime: a) the defendant introduced one or more drugs into interstate commerce b) the drugs were misbranded; and c) the defendant acted with intent to mislead an agency of the United States.

FACTUAL BASIS

4. The defendant and the government agree to the following facts, which form the basis for the entry of the guilty plea, including relevant conduct.

During the period of February 2007 through September 2009:

a) The defendant was a citizen and resident of Canada and was a physician licensed to practice medicine in the Province of Ontario. The defendant was not licensed to practice medicine in the United States. The defendant operated a medical practice in Etobicoke, Ontario, known as the Institute of Sports Medicine Health and Wellness Centre (ISM). Mary Anne Catalano was employed at ISM and worked as an assistant to the defendant.

b) The defendant traveled to the United States from Canada on numerous occasions to treat patients here. Sometimes the defendant was accompanied by Ms. Catalano to assist him; sometimes he and Ms. Catalano traveled separately and the defendant met Ms. Catalano in the United States; and on other occasions the defendant traveled to the United States alone and treated patients here without Ms. Catalano being present. Patients the defendant treated in the United States were professional athletes, including but not limited to players on teams in the National Football League and Major League Baseball.

c) On numerous occasions the defendant and Ms. Catalano entered the United States at the Peace Bridge Port of Entry in Buffalo, New York. The defendant entered the United States numerous other times via air travel from Toronto to various cities in the United States. On some occasions, after entering the United States, the defendant traveled within the United States to different places to provide medical treatments to professional athletes. Among the places to which the defendant traveled for this purpose were Hawaii, Cleveland, New York City, Miami, Tampa, Orlando, Washington, D.C., Boston, Atlanta, San Diego, San Francisco, Denver, and Phoenix.

d) When the defendant and Ms. Catalano traveled separately to the United States, Ms. Catalano carried medical supplies based upon a checklist she prepared based on the defendant's instructions. Some of the items on the checklist were Nutropin, Actovegin, ATP, ginseng, Celebrex, IV tubing, a centrifuge, plasma kits, and sterile gloves. The defendant and Ms. Catalano understood that if Ms. Catalano were asked by U.S. border officers about the purpose for her entry into the United States with the medical supplies, she would respond that she was attending a medical conference where the defendant would speak and demonstrate the use of medical supplies. The defendant and Ms. Catalano knew, however, that on the majority of the occasions they came to the United States their only purpose for coming to the U.S. was to provide medical treatments to the defendant's patients. Some of the medical supplies the defendant and Ms. Catalano brought into the United States for these treatments, including Nutropin and Actovegin, were misbranded drugs within the meaning of U.S. law.

e) The defendant provided the treatments listed below to his patients while in the United States. Individual patients did not necessarily receive all or more than one of these treatments.

- 1) "Anti-inflammatory IVs," i.e., intravenous treatments involving a mixture containing Actovegin (a substance derived from calf's blood), and Adenosine Triphosphate (ATP), Traumeel, magnesium, calcium, vitamins C, B-100, B-6, and Glutathione;

- 2) Plasma Rich Platelet ("PRP") treatments, which involved extracting blood from patients, spinning the blood in a centrifuge to separate the plasma from the red blood cells, and re-injecting the plasma into the patients for the purpose of accelerating the healing process.

- 3) Injections containing a mixture of substances including Actovegin, Traumeel, Vitamin B-12 and (in the case of chronic injuries) Zeel, as treatment for injured muscles; and

4) Injections containing a mixture of substances including Nutropin, a human growth hormone (HGH) produced by recombinant DNA technology, Traumeel, Procaine, Zeel, and vitamin B-12 injected into the knee and given for the purpose of treating joint inflammation.

f) The defendant also from time to time, while in the United States, distributed and administered substances such as ATP for intramuscular injections. Items used for intramuscular injections were labeled in languages other than English.

g) Prescription items distributed by the defendant, including but not limited to Nutropin, did not bear the "RX only" symbol required by U.S. law and FDA regulations. Under U.S. law and FDA regulations, substances intended for use in the cure, mitigation, treatment or prevention of disease in man, and articles intended to affect the structure or function of the body of man, as well as articles intended for use as components of such items, are "misbranded" if they are not approved by the FDA and labeled in the English language. The forms of Actovegin used as ingredients in the anti-inflammatory IVs and in the injections for injured muscles were not labeled in the English language but instead were labeled in German or Russian.

h) Nutropin was not approved by the FDA for the uses intended by the defendant and was approved only for a limited number of uses, which did not include the treatment of adults for inflammation of joints. Actovegin was not approved by the FDA for any use.

i) The defendant administered medical treatments in the United States in such places as the homes of patients and in hotel rooms. The cost of the treatments, travel, lodging, and other expenses for the defendant and Ms. Catalano were charged to the patients. The amount the defendant charged to the patients during the aforementioned time period was approximately \$800,000. For the purposes of this Plea Agreement, the defendant and the government agree that the value of the substances provided to the patients which contained unapproved and/or misbranded substances exceeded \$30,000 but did not exceed \$70,000.

(j) On or about August 27, 2009, the defendant and Ms. Catalano traveled to the United States separately. Ms. Catalano entered the United States at the Peace Bridge and the defendant traveled to the United States from Toronto by air. The purpose of the defendant's entry into the United States was to provide medical treatments to several athletes.

(k) On September 14, 2009, Mary Anne Catalano attempted to enter the United States at the Peace Bridge in Buffalo, New York, and was referred to secondary inspection. During secondary inspection, Ms. Catalano told an Officer from the Department of Homeland Security, Customs and Border Protection (CBP), that she was traveling to Washington, D.C. to attend a medical conference with her employer, the defendant. Ms. Catalano further stated to the CBP Officer that she had items intended for display at the medical conference. Ms. Catalano made these statements pursuant to an understanding she had with the defendant that she would falsely tell U.S. border personnel that she and the defendant would be attending a medical conference in the United States. A duffle bag in Ms. Catalano's vehicle contained medical items such as needles, syringes, a centrifuge, numerous bottles, including a bottle of Nutropin and bottles of Actovegin. In fact Ms. Catalano's purpose for coming to the United States was to meet the defendant in Washington D.C., where the defendant was to provide medical treatment to a professional athlete.

### III. SENTENCING GUIDELINES

5. The defendant understands that the Court must consider but is not bound by the Sentencing Guidelines (Sentencing Reform Act of 1984).

BASE OFFENSE LEVEL

6. The government and the defendant agree that Guidelines §§ 2N2.1(c)(1) and 2B1.1(a)(2) apply to the offense of conviction and prescribe a base offense level of 6.

SPECIFIC OFFENSE CHARACTERISTICS  
U.S.S.G. CHAPTER 2 ADJUSTMENTS

7. The government and the defendant agree that the offense level will be increased by six-levels pursuant to Guidelines §2B1.1(b)(1)(D) and Application Note 3(F)(v)(III), because the value of items administered and sold which required government regulation but which had not received it exceeded \$30,000 and did not exceed \$70,000.

U.S.S.G. CHAPTER 3 ADJUSTMENTS

8. The government and the defendant agree that the following adjustments to the base offense level do apply:

- a. The two-level upward adjustment of Guidelines § 3B1.1(c) (supervisor of criminal activity;
- b. The two-level upward adjustment of Guidelines § 3B1.3 (abuse of a special skill); and
- c. The two-level upward adjustment of Guidelines § 3C1.1 (obstruction of justice).

9. Based on the foregoing, it is the understanding of the government and the defendant that the adjusted offense level for the offense of conviction is 18.

**ACCEPTANCE OF RESPONSIBILITY**

10. At sentencing, the government agrees not to oppose the recommendation that the Court apply the two level downward adjustment of Guidelines § 3E1.1(a) (acceptance of responsibility), and further agrees to move the Court to apply the additional one level downward adjustment of Guidelines § 3E1.1(b), which would result in a total offense level of 15.

**CRIMINAL HISTORY CATEGORY**

11. It is the understanding of the government and the defendant that the defendant's criminal history category is I. The defendant understands that if he is sentenced for or convicted of any other charges prior to sentencing in this case, his criminal history category may increase. The defendant understands that he has no right to withdraw his guilty plea on account of the Court's determination of his criminal history category.

**GUIDELINES' APPLICATION, CALCULATIONS AND IMPACT**

12. It is the understanding of the government and the defendant that, with a total offense level of 15 and criminal



history category of I, the defendant's sentencing range would be a term of imprisonment of 18 to 24 months, a fine of \$4,000 to \$40,000, and a period of supervised release of one year. Notwithstanding this, the defendant understands that at sentencing the defendant is subject to the maximum penalties set forth in paragraph 1 of this agreement.

13. The government and the defendant agree to the Sentencing Guidelines calculations set forth in this agreement, and neither party will advocate or recommend the application of any other Guideline, or move for any Guidelines departure, or move for or recommend a sentence outside the Guidelines, except as specifically set forth in this agreement. A breach of this paragraph by one party will relieve the other party of any agreements made in this plea agreement with respect to sentencing motions and recommendations. A breach of this paragraph by the defendant shall also relieve the government from any agreements to dismiss or not pursue additional charges.

14. The defendant specifically reserves the right to argue for a non-Guidelines sentence outside the otherwise applicable Guidelines range pursuant to Title 18, United States Code, Section 3553(a). The government reserves the right to oppose this motion.

15. The defendant understands that the Court is not bound to accept any Sentencing Guidelines calculations set forth in this agreement, and the defendant will not be entitled to withdraw his guilty plea on account of the sentence imposed by the Court.

#### IV. STATUTE OF LIMITATIONS

16. In the event that the defendant's guilty plea is withdrawn, or conviction is vacated, either pre- or post-sentence, by way of appeal, motion, post-conviction proceeding, collateral attack or otherwise, the defendant agrees that any charges dismissed pursuant to this agreement shall be automatically reinstated upon motion of the government and further agrees not to assert the statute of limitations as a defense to any other criminal offense involving or related to the facts set forth in the Factual Basis in Section II of this Plea Agreement. This waiver shall be effective for a period of six months following the date upon which the withdrawal of the guilty plea or vacating of the conviction becomes final.

#### V. ALIEN STATUS

17. The defendant acknowledges that because he is not a citizen of the United States, he is subject to the laws, regulations and associated policies of the Bureau of Citizenship

and Immigration Services. The defendant has had a full opportunity to explore the ramifications, if any, that his guilty plea may have upon his status in the United States, including but not limited to his right to enter, work, and/or be employed in the United States. The defendant has fully discussed this with his attorney and is satisfied that his guilty plea is in his best interests. Any effect upon the defendant's immigration status is a separate issue that will be determined through the laws, regulations and associated policies, processes and procedures of the Department of Homeland Security.

18. The defendant further acknowledges that, because he is a citizen of Canada who is charged in an indictment alleging that the defendant has committed crimes in the United States, the government may seek the defendant's extradition from Canada to stand trial in the United States. The defendant, however, has agreed to come to the United States voluntarily for the purpose of entering a guilty plea pursuant to this Plea Agreement without being subject to extradition proceedings or to any order of extradition.

#### VI. GOVERNMENT RIGHTS AND RESERVATIONS

19. The defendant understands that the government has reserved the right to:

- a. provide to the Probation Office and the Court all the information and evidence in its

possession that the government deems relevant concerning the defendant's background, character and involvement in the offense charged, the circumstances surrounding the charge and the defendant's criminal history;

b. respond at sentencing to any statements made by the defendant or on the defendant's behalf that are inconsistent with the information and evidence available to the government;

c. modify its position with respect to any sentencing recommendation or sentencing factor under the Guidelines including criminal history category, in the event that subsequent to this agreement the government receives previously unknown information regarding the recommendation or factor; and

d. oppose any application for a sentence outside the Guidelines range made by the defendant.

20. The defendant agrees that any financial records and information provided by the defendant to the Probation Office, before or after sentencing, may be disclosed to the United States Attorney's Office for use in the collection of any unpaid financial obligation.

21. At sentencing, the government will move to dismiss the open counts of the Indictment.

#### **VII. APPEAL RIGHTS**

22. The defendant understands that Title 18, United States Code, Section 3742 affords a defendant a limited right to appeal

the sentence imposed. The defendant, however, knowingly waives the right to appeal and collaterally attack any component of a sentence imposed by the Court which falls within or is less than the sentencing range for imprisonment, a fine and supervised release set forth in Section III, paragraph 12 above, notwithstanding the manner in which the Court determines the sentence. In the event of an appeal of the defendant's sentence by the government, the defendant reserves his right to argue the correctness of his sentence.

23. The defendant understands that by agreeing not to collaterally attack the sentence, the defendant is waiving the right to challenge the sentence in the event that in the future the defendant becomes aware of previously unknown facts or a change in the law which the defendant believes would justify a decrease in the defendant's sentence.

24. The government waives its right to appeal any component of a sentence imposed by the Court which falls within or is greater than the sentencing range for imprisonment, a fine and supervised release set forth in Section III, paragraph 12 above, notwithstanding the manner in which the Court determines the sentence. However, in the event of an appeal from the defendant's

sentence by the defendant, the government reserves its right to argue the correctness of the defendant's sentence.

#### VIII. COOPERATION

25. The defendant will cooperate with the government by voluntarily appearing in the United States on the indictment in this action, entering a guilty plea pursuant to this Plea Agreement, and providing complete and truthful information regarding the defendant's knowledge of any and all criminal activity, whether undertaken by the defendant or others, in any way involving or related to the facts set forth in Section II, paragraph 4 of this Plea Agreement and the defendant's treatment of patients in the United States and providing materials to them. The defendant's cooperation shall also include testifying truthfully and completely before such grand jury and in such pre-trial and trial proceedings as the government shall deem necessary.

26. The defendant's cooperation shall also be provided to any local, state or federal authorities designated by the government and who have agreed to abide by the terms of the "Cooperation" section of this agreement. The defendant's obligation to testify truthfully and completely shall extend to proceedings in local, state and federal courts in jurisdictions which have agreed to abide by this agreement.

27. In exchange for the defendant's plea of guilty and cooperation as set forth in this agreement, the defendant will not be prosecuted by the Office of the United States Attorney for the Western District of New York for any other federal criminal offenses committed in the Western District of New York in any way involving or related to the facts set forth in Section II, paragraph 4 of this Plea Agreement, committed up to the date of this agreement and about which the defendant provides complete and truthful information.

28. Further, no testimony, statements or tangible objects provided by the defendant in compliance with this agreement (or any information directly or indirectly derived therefrom) will be used against the defendant in any criminal case, except a prosecution for perjury or making false statements.

29. Upon condition that the defendant has fully complied with all terms and conditions of this agreement, should the government determine that the defendant has provided substantial assistance in the investigation or prosecution of other persons who have committed offenses, the government will move the Court at sentencing to depart downward from the Guidelines 2 levels as provided for in Guidelines § 5K1.1, and pursuant to Guidelines § 5K2.0 on the ground that the defendant assisted the government by

agreeing to appear voluntarily in the United States to enter a plea of guilty and by not requiring extradition from Canada, which if granted by the Court would result in a total offense level of 13 and sentencing range for imprisonment of 12 to 18 months. The defendant understands that the decision to make such a motion is within the sole discretion of the government and that the decision to grant such a motion, and the extent of any downward departure, are matters solely within the discretion of the Court.

30. This agreement does not preclude the prosecution of the defendant for perjury or making false statements in the event the defendant testifies falsely or provides false information to the government. This agreement is not contingent upon the filing of charges against, the return of an Indictment against, or the successful prosecution of, any person or entity.

31. It is a condition of this agreement that, up through the date of the defendant's sentencing, the defendant shall commit no further crimes. It is also a condition of this agreement that the defendant must, at all times, give complete, truthful and accurate information and testimony and not withhold information from the government or refuse to testify truthfully and completely. Should the defendant be sentenced prior to the completion of the defendant's cooperation with the government, the defendant's



obligation to comply with the cooperation provisions of this agreement extends past sentencing.

32. In the event the government believes the defendant has violated any of the conditions of the "Cooperation" section of this agreement, the government, in addition to its other rights as set forth in the "Cooperation" section of this agreement, reserves the right: (a) to modify any recommendation the government agreed to make in a motion pursuant to Guidelines § 5K1.1 and/or Title 18, United States Code, Section 3553(e); and (b) to petition the Court, before or after sentencing, for an order declaring that the defendant has breached the "Cooperation" section and relieving the government of its obligations under this section.

33. In the event the government petitions the Court to declare that the defendant has breached the "Cooperation" section of this agreement, whether the defendant has violated any of the conditions of the "Cooperation" section shall be determined by the Court in an appropriate proceeding at which any disclosures and documents provided by the defendant shall be admissible and at which the government shall be required to establish any violation by a preponderance of the evidence. In order to establish any violation by the defendant, the government is entitled to rely on

statements and information given by the defendant pursuant to this agreement.

34. If the "Cooperation" section of this agreement is declared breached by the Court:

- a. the defendant shall thereafter be subject to prosecution for any federal criminal violations of which the government has knowledge, including but not limited to, perjury and obstruction of justice;
- b. the government may withdraw any motion filed pursuant to Sentencing Guidelines § 5K1.1, Title 18, United States Code, Section 3553(e) and/or Rule 35(b);
- c. the defendant has no right to withdraw the plea of guilty;
- d. the defendant shall waive all rights under Fed. R. Crim. P. 11(f), Fed. R. Evid. 410 and Sentencing Guidelines § 1B1.8 and the defendant expressly agrees that all statements, testimony and tangible objects provided by the defendant (with the exception of statements made in open court during guilty plea proceedings), whether prior or subsequent to this agreement, can be used directly and indirectly in any and all criminal proceedings against the defendant; and
- e. the defendant agrees that any charges that were dismissed pursuant to this agreement shall be automatically reinstated upon motion of the government. Furthermore, the defendant agrees not to assert the statute of limitations as a defense to any criminal offense involving or related to the facts set forth in Section II (the factual Basis) of this Plea Agreement that is not time barred as of the date of this agreement. This waiver shall be effective for a period of six months following the date upon which the Court's order declaring the agreement breached by the defendant becomes final.

35. At the time of sentencing, the government will make the nature and extent of the defendant's compliance with this agreement known to the Court. The government and the defendant will request that sentencing be adjourned until full satisfaction by the defendant of the terms of this agreement. In the event the defendant is sentenced prior to the completion of the defendant's cooperation with the government, the government reserves the right to modify any recommendation to be made by the government at sentencing pursuant to Guidelines § 5K1.1 and/or Title 18, United States Code, Section 3553(e).

36. The defendant's attorneys are permitted to be present at any time the defendant is questioned or interviewed by government agents regarding the matters set forth in this agreement.

#### **IX. FORFEITURE PROVISIONS**

37. The defendant agrees not to contest the civil forfeiture to the United States of the following asset:

The sum of Two Hundred Seventy-five Thousand (\$275,000.00) Dollars by means of a bank draft payable in U.S. funds to the U.S. Department of Homeland Security, Customs and Border Protection, said payment to be made prior to the first scheduled sentencing date set by the Court.

38. The defendant acknowledges that the government will commence a civil forfeiture action against the property identified

in ¶37 above. The defendant agrees not to contest the forfeiture of the defendant's interest in the property described above to the United States pursuant to Title 18, United States Code, Section 981 (a)(1)(C). The defendant agrees that he has no legal right to retain said property. The defendant further agrees to enter into any stipulations settling the civil forfeiture action and to execute any other documents determined to be necessary by the government to properly forfeit the property listed above to the United States of America. The defendant further agrees to the entry of an Order of Civil Forfeiture pursuant to Title 18, United States Code, Section 981.

39. The defendant agrees to waive any claim or defense under Rule 41(g) of the Federal Rules of Criminal Procedure and the Eighth Amendment to the United States Constitution, including any claim of excessive fine regarding the forfeiture of assets by the United States, the State of New York or its subdivisions.

40. The defendant agrees that forfeiture of the aforementioned property as set forth in this agreement shall not be deemed an alteration of the defendant's sentence. Forfeiture of the defendant's assets shall not be treated as satisfaction of any fine, restitution, cost of imprisonment, or any other penalty the Court may impose upon the defendant in addition to forfeiture.


41. The defendant waives any right to appeal or collaterally attack any matter in connection with the forfeiture of assets as provided in this agreement and understands that the forfeiture provisions will remain in full force and effect in the event this Plea Agreement is vacated at any point in time.

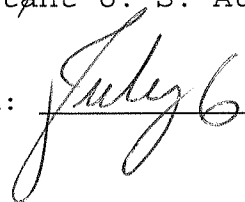
**X. TOTAL AGREEMENT AND AFFIRMATIONS**

42. This plea agreement represents the total agreement between the defendant and the government. There are no promises made by anyone other than those contained in this agreement. This agreement supersedes any other prior agreements, written or oral, entered into between the government and the defendant.

WILLIAM J. HOCHUL, JR.  
United States Attorney  
Western District of New York

BY:


  
PAUL J. CAMPANA  
Assistant U. S. Attorney

Dated: , 2011

I have read this agreement, which consists of 22 pages. I have had a full opportunity to discuss this agreement with my attorney, Mark J. Mahoney, Esq. I agree that it represents the total agreement reached between myself and the government. No promises or representations have been made to me other than what is contained in this agreement. I understand all of the consequences of my guilty plea. I fully agree with the contents of this agreement. I am signing this agreement voluntarily and of my own free will.

  
\_\_\_\_\_  
ANTHONY GALEA  
Defendant

Dated: July 4, 2011

  
\_\_\_\_\_  
MARK J. MAHONEY, ESQ.  
Attorney for the Defendant

Dated: July 6, 2011